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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,356	11/21/2000	Shimpei Ushio	USHIO-2	8174

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/716,356	USHIO ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently, claims 1, 2, 4-9, and 19 are pending and under consideration.

2. In the prior action, the Final action mailed on September 21, 2005, claims 1, 2, 4-9, and 18-52 were pending in the application, with claims 1, 2, and 4-9, and 19 indicated as allowable; claims 18 and 20-52 rejected. In the After-Final Response of January 20, 2006, the Applicant cancelled claims 18 and 20-52.

3. In view of the new rejections presented below, the Finality of the prior action is withdrawn.

Claim Objections

4. **(Prior Objection- Withdrawn)** Claims 22-52 were objected to in the prior action. In view of the cancellation of these claims from the application, the objection is withdrawn.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Withdrawn)** Claims 18, 20, and 21-52 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a

composition comprising SEQ ID NO: 6, or for derivatives thereof varying from SEQ ID NO: 6 by one amino acid residue, does not reasonably provide enablement for a composition comprising any homologue of the sequence that maintains the biological activities and other characteristics required by claim 18. In view of the cancellation of these claims from the application, the rejection is withdrawn.

7. **(Prior Rejection- Withdrawn)** Claims 18, 20, and 21-52 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as lacking sufficient written description support for the genus comprising any homologue of SEQ ID NO: 6 that meets each of the identified functional limitations. In view of the cancellation of these claims from the application, the rejection is withdrawn.

8. **(New Rejection)** Claims 1 and 4-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn, in part, to polypeptides comprising contiguous fragments of SEQ ID NO: 6 wherein said fragments induce interferon-γ production in immunocompetent cells.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical

> and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus may be found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In the instant case, the claims are drawn to a genus of polypeptides comprising fragments of SEQ ID NO: 6 that are described as having the function of inducing interferon-γ production. However, the present application does not provide sufficient written description support to demonstrate possession of this genus.

The application discloses two functionally related proteins, one murine (SEQ ID NO: 4) and one human (SEQ ID NO: 6), that induce interferon-γ production in, respectively, murine or human cells. However, while the application refers to fragments of such polypeptides that induce interferon-γ production (pages 9-10), and discusses protein sequences that represent fragments of the polypeptide of SEQ ID NO: 6 (see e.g., page 15), the application nowhere discloses any examples fragments of SEQ ID NO: 6 that are disclosed as having the ability to induce interferon-γ production. As the application does not provide any representative species, such cannot be relied on to provide descriptive support to demonstrate possession of the genus.

In addition to the lack of any species of the claimed genus, the application also fails to provide any other non-functional description of the claimed fragments. As was indicated above,

the application does disclose fragments of SEQ ID NO: 6, but provides no indication as to whether such fragments are able to induce interferon-γ production. Nor is there any identification of any structural feature or sequence that correspond to the ability of a given fragment to perform the required function. While the application does disclose two separate proteins (the human protein of SEQ ID NO: 6, and its murine homolog), a comparison of the sequences shows no region of clear homology such that it could be identified as the functional site. See e.g., Kim et al., JBC, 277:10998-11003, at 11000 Figure 1 (showing the human and murine sequences next to each other). Because, the application provides no identification of any specific structure or sequence that correlates to the required function, the application provides insufficient information to demonstrate possession of the claimed fragments.

Thus, because the claims read on genus of polypeptides that have a functional limitation without providing any demonstration of possession of the claimed genus, either through species disclosure or identification of a structure correlating to the function, the claims are rejected as reading on a genus for which there is insufficient written description support.

The rejection is not applied against claims 2 or 19 because, although the claims read on fragments of SEQ ID NO: 6, the claims also require that the polypeptide in the composition, whether of SEQ ID NO: 6 or a fragment thereof, meets a molecular weight limitation. Thus, the "fragment" of SEQ ID NO: 6 permitted in claim 19 are limited to the deletion of no more than a few amino residues from one or both of the protein terminuses. It is further noted that because the claim reads on "a fragment thereof" the claim indicates that the fragment is a single contiguous fragment rather than a combination of fused fragments- thereby excluding internal deletions.

Double Patenting

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10. **(New Rejection)** Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 29 of prior U.S. Patent No. 6,214,584. This is a double patenting rejection.

Claim 1 is drawn to three separate inventions, and is therefore legal shorthand for three separate claims. The first of these inventions is the polypeptide of SEQ ID NO: 6 wherein the amino acid at position 73 is Ile or Thr. The same polypeptide is claimed in claim 29 of the 584 patent (identified as SEQ ID NO: 1, instead of SEQ ID NO: 6). Because the application claim 1 a) reads on identical subject matter to the patent claim, claim 1 is rejected for statutory double patenting over claim 29 of the patent.

Conclusion

11. Claim 19 appears allowable over the art. Claim 2 is objected to a depending from a rejected claim.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

3/1/06

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